4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2826]

# Allergan Sales, LLC, et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

| Application No. | Drug | Applicant |
|---|---|---|
| ANDA 040099 | Norco (hydrocodone bitartrate and acetaminophen) Tablets, 5 milligrams (mg)/325 mg. | Allergan Sales, LLC, U.S. Agent for Allergan Pharmaceuticals International Limited, 5 Giralda Farms, Madison, NJ 07940. |
| ANDA 040148 | Norco (hydrocodone bitartrate and | Do. |

| Application No. | Drug | Applicant |
|---|---|---|
| | acetaminophen) Tablets, 2.5 mg/325 mg, 5 mg/325 mg, 7.5 mg/325 mg, 10 mg/325 mg, and 10 mg/500 mg. | |
| ANDA 076434 | Chlorhexidine Gluconate Solution, 0.12%. | Sunstar Americas, Inc., 301 East Central Rd., Schaumburg, IL 60195. |
| ANDA 079076 | Ranitidine Hydrochloride (HCl) Injection, Equivalent to (EQ) 25 mg base/milliliters (mL). | Mylan Pharmaceuticals Inc., a Viatris Company, U.S. Agent for Mylan Laboratories Limited, 3711 Collins Ferry Rd., Morgantown, WV 26505. |
| ANDA 090054 | Ranitidine HCl Syrup, EQ 15 mg base/mL. | Tolmar Inc., 701 Centre Ave., Fort Collins, CO 80526. |
| ANDA 201804 | Letrozole Tablets, 2.5 mg. | Indicus Pharma, LLC, 2530 Meridian Parkway, Durham, NC 27713. |
| ANDA 201832 | Nimodipine Capsules, 30 mg. | Sofgen Pharmaceuticals, LLC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180. |
| ANDA 203419 | Donepezil HCl Tablets, 23 mg. | Indicus Pharma, LLC |
| ANDA 203519 | Morphine Sulfate Solution, 20 mg/5 mL. | Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852. |
| ANDA 206151 | Abacavir Sulfate and Lamivudine Tablets, EQ 600 mg base; 300 mg. | Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Limited, 279 Princeton-Hightstown Rd., East Windsor, NJ 08520. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have

reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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